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California Department of Public Health



EDMUND G. BROWN, JR.
Governor

December 16, 2014

AFL 14-34

TO: General Acute Care Hospitals (GACHs)
Acute Psychiatric Hospitals (APHs)

SUBJECT: Pharmaceutical Service Changes Made by Senate Bill (SB) 1039

AUTHORITY: Health and Safety Code (HSC) Sections 1250.06, 11150, 11210;
Business & Professions Code (BPC) Sections 4115, 4119.6, 4119.7

This All Facilities Letter (AFL) provides notice of the enactment of SB 1039 (Chapter 319, Statutes of 2014), effective January 1, 2015.

SB 1039 makes the following changes regarding the provision of pharmaceutical services in GACHs:

- **Pharmacy Technicians.** A pharmacy technician, working under the direct supervision and control of a pharmacist in a GACH, may perform any of the following duties:
 - packaging emergency supplies for use in the GACH and the hospital's emergency medical system, or as authorized by BPC section 4119 regarding the furnishing of dangerous drugs/devices for emergency pharmaceutical supply containers;
 - sealing emergency containers for use in the GACH; and
 - performing monthly checks of the drug supplies stored throughout the GACH, with irregularities being reported within 24 hours to the pharmacist in charge and the director or the chief executive officer of the facility in accordance with the facility's policies and procedures (P&Ps).
- **Intern Pharmacists.** Intern pharmacists under the direct supervision and control of a pharmacist may:
 - stock, replenish, and inspect the emergency pharmaceutical supplies container and the emergency medical system supplies of a GACH;
 - inspect the drugs maintained in the GACH at least once per month, with the facility being required to establish specific written P&Ps for such inspections.

- *Furnishing Dangerous Drugs or Dangerous Devices*. A hospital pharmacy servicing a GACH may furnish a dangerous drug or dangerous device pursuant to preprinted or electronic standing orders, order sets, and protocols established under the facility's P&Ps as approved according to the policies of the facility's governing board, if the order is dated, timed, and authenticated in the medical record of the patient to whom the dangerous drug or device will be provided.
- *Storage and Maintenance of Drugs*. A GACH shall store and maintain drugs in accordance with national standards regarding the storage areas and refrigerator and freezer temperatures, and otherwise pursuant to the manufacturer's guidelines. Nationally recognized standards would include:
 - *U.S. Pharmacopeial Convention (USP 34)*, General Notices and Requirements (link: http://www.usp.org/sites/default/files/usp_pdf/EN/USPNF/USP34-NF29General%20Notices.pdf), Section 10: Preservation, Packaging, Storage and Labeling.
 - Centers for Disease Control and Prevention: *Vaccines and Immunizations* (link: <http://www.cdc.gov/vaccines/pubs/pinkbook/vac-storage.html>), the best practice guidance for the storage and handling of vaccines.

The facility's P&Ps must specify the above storage parameters.

SB 1039 makes the following change regarding the provision of pharmaceutical services in both GACHs and APHs:

- Facilities must adopt P&Ps regarding the responsibility for ensuring proper methods of repackaging and labeling of bulk cleaning agents, solvents, chemicals, and nondrug hazardous substances used throughout the hospital. Contrary to Sections 70263(s) and 71233(s) of Title 22 of the California Code of Regulations (CCR), GACHs and APHs will no longer be required to consult a pharmacist regarding the repackaging and labeling of these substances, except for areas where sterile compounding is performed.

Several sections of SB 1039 address topics already covered by Title 22. In some instances, the statutory change conflicts with those regulations. Until the department can promulgate revisions to Title 22 that reflect the changes made by SB 1039, facilities seeking to follow the BPC provisions must request and receive program flexibility from their local district office. In order to help facilities identify those conflicts, a comparison table is attached to this AFL. Facilities must submit all program flexibility requests in writing and include supporting documentation such as proposed policies and procedures. The program flexibility request form can be found at the link below.

<http://www.cdph.ca.gov/pubsforms/forms/CtrlForms/cdph5000.pdf>

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Please note that facilities are responsible for following all applicable laws. Any failure of the California Department of Public Health to expressly notify facilities of statutory or regulatory requirements does not relieve facilities of their responsibility for following all laws and regulations. Facilities should refer to the full text of all applicable sections of the HSC, the BPC, and Title 22 of the CCR to ensure compliance.

If you have questions regarding any of the matters discussed in this AFL, please contact your local district office.

Sincerely,

Original signed by Jean Iacino

Jean Iacino
Interim Deputy Director

[Attachment](#)